The stewardship objective of Federal financial reporting requires reporting on the Federal Government's accountability over certain resources entrusted to it and certain responsibilities assumed by it that cannot be measured in traditional financial reports. Stewardship investments are substantial investments made by the Federal Government for the benefit of the nation. When incurred, they are treated as expenses in determining the net cost of operations. However, these items merit special treatment so that readers of Federal financial reports know the extent of investments that are made for long-term benefit. Federally financed research and development is a stewardship investment that should be measured in terms of expenses.

Research and development includes those expenses for basic research, applied research, and development that are intended to increase or maintain the national economic productive capacity or yield other benefits. FDA has two programs that meet the requirements of research and development investments: Orphan Products Development (OPD) Program and FDA Research Grants Program. While FDA's center components conduct scientific studies, FDA does not consider this type of research as "research and development" because it is used to support FDA's regulatory policy and decision-making processes.

Orphan Products Development Program

The OPD Program was established by the Orphan Drug Act (PL 97-414, as amended) with the purpose of identifying orphan products and facilitating their development. An orphan product is a drug, biological product, medical device, or medical food that is intended to treat a rare disease or condition (i.e., one with a prevalence of fewer than 200,000 people in the United States).

The Office of Orphan Products Development (OOPD) operates the OPD Program by administering an orphan product designation process, providing research study design assistance to sponsors of orphan products, encouraging sponsors to conduct open protocols (allowing patients to be added to ongoing studies), and managing a clinical research grants program. The OPD Program has been very successful with more than 269 drugs and biological products for rare diseases have been brought to market since 1983.

The Orphan Drug Act provides for granting special status to a product/indication combination upon a request of a sponsor, and if the product/indication combination meets certain criteria. This status is referred to as orphan designation. Orphan designation qualifies the sponsor to receive certain benefits (i.e., tax credit and exclusive marketing rights) from the Government in exchange for developing the orphan product.

OOPD also administers a clinical research grants program whose goal is to provide clinical

development of products for use in rare diseases or conditions where no current therapy exists or where current therapy would be improved. OOPD provides grants to conduct clinical studies intended to provide data acceptable to FDA that will either result in or substantially contribute to the approval of these products under the Federal Food, Drug, and Cosmetics Act.

New and continuing OPD studies strive to provide information on human safety and effectiveness of products for diseases and conditions such as dystonia, sickle cell disease, acute leukemia, cystic fibrosis, adrenoleukodystrophy, and tyrosinemia. The majority of research expenses are for salaries, wages, and non-payroll patient care costs.

Research Grants Program

The FDA Research Grants Program is a grants program listed as No. 93-103 under the *Catalog of Federal Domestic Assistance*, whose purpose is assist public and non-public institutions and for-profit organizations to establish, expand, and improve research, demonstration, education, and information dissemination activities concerned with a wide variety of FDA areas.

Research areas include: acquired immunodeficiency syndrome, biologics, blood and blood products, therapeutics, vaccines, allergenic projects, drug hazards, human and veterinary drugs, clinical trials on drugs and devices for orphan products development, nutrition, sanitation, microbiological hazards, medical devices and diagnostic products, radiation emitting devices and material, food safety, and food additives. Participating with the research grants are colleges, universities, profit-making organizations, nonprofit institutions, hospitals, and State and Local governments.

Examples of funded projects include: Radiation Effects and Exposure Criteria; Analytical Methodology for Animal Drug Tissue in Milk; Post Marketing Surveillance of Adverse Drug Reactions; International Program on Chemical Safety; Tobramycin for Inhalation in Patients with Cystic Fibrosis; Interferon Gamma Treatment of Osteoporosis; and Small Business Innovation Research: Phase 1 - Detection of Campylobacteria in Foods, Phase II - Point of Care Lead Instrument and Sensor.

Expenses

The following table presents the total expenses incurred in the FY's 2000-2004 (including expenses related to the OPD Program's administration, Office of the Commissioner overhead, and grants awarded in previous fiscal years) for each of FDA's research and development activities:

U.S. Department of Health and Human Services

Food and Drug Administration

RESEARCH & DEVELOPMENT
REQUIRED SUPPLEMENTARY STEWARDSHIP INFORMATIOM
For the Years Ended September 30, 2004 and 2003
(Unaudited)

Research and Development Expenses
(In Thousands)

PROGRAM	TYPE	Fiscal Year				
		04	**03**	**02**	**01**	**00**
Orphan Product Development	Development	$1,772	$6,278	$5,961	$2,770	$3,070
Orphan Product Research Grants	Applied Research	--	--	--	2,273	17,794
Research Grants Program (excluding Orphan Product grants)	Applied Research	26,108	25,387	22,994	20,813	4,752
Total		**$27,880**	**$31,665**	**$28,995**	**$25,856**	**$25,616**

NOTE:

Orphan Product Research Grant expenses are combined with Orphan Product Development for FY 2002 because it has been determined that it does not meet the definition of research.